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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Nathan S. Lewis *et al.*

Application No.: 09/409,644

Filed: October 1, 1999

For: CONDUCTIVE ORGANIC SENSORS, ARRAYS AND METHODS OF USE

Group Art Unit: 1743

Examiner: Arlen Soderquist

Appeal No.: 1

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By: Kim A. Cabello

SUBSTITUTE REPLY BRIEF

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Sir:

This appeal is from the decision of the Primary Examiner dated April 20, 2004, finally rejecting claims 98-110, 112-123 and 126-159. An Appeal Brief was submitted on November 5, 2004 (incorporated herein by reference in its entirety), perfecting the Notice of Appeal originally mailed on August 20, 2004.

Prosecution in the application was re-opened by the Examiner on January 25, 2005. A Supplemental Appeal Brief was filed pursuant to 37 C.F.R. §41.31 and MPEP § 1208.02 along with a Request for Reinstatement of the Appeal on April 25, 2005.

The Examiner filed an Examiner's Answer Brief on July 22, 2005.

Appellants filed a Reply Brief along with a timely Request for Oral Hearing on September 22, 2005.

The Examiner filed a Supplemental Examiner's Answer on December 9, 2005.

The Board of Patent Appeals and Interferences returned the pending Appeal to the Examiner as a Non-compliant Brief for compliance with formalities on October 25, 2006.

Appellants submitted a Response to the Non-compliant Brief on November 13, 2006, labeling Appendices but providing no other substantive changes.

The Examiner filed a Substitute Examiner's Answer on March 19, 2007.

The present Reply is in response to the Substitute Examiner's Answer of March 19, 2007.

No fee is believed to be due for consideration of this Reply Brief. However, the Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

(1) Real Parties in Interest

The Real Parties in Interest are as set forth previously and agreed to by the Examiner.

(2) Related Appeals and Interferences

There are no known related appeals or interferences.

(3) Status of Claims

The status of the claims is as set forth previously and agreed to by the Examiner.

(4) Status of Amendments

The status of amendments is as set forth previously and agreed to by the Examiner.

(5) Summary Claimed Subject Matter

The summary of claimed subject matter is as set forth previously and agreed to by the Examiner.

(6) Grounds of Rejection to be Reviewed on Appeal

The grounds of rejection are as set forth in the first Appeal Brief filed November 5, 2004. The Examiner has withdrawn the rejection over the cited reference of de Lacy Costello.

(a) Prior Grounds of Rejection

The Examiner has alleged that claims 98-110, 112-113, 115, 117-123, 126-135, 137, 139-157 and 159 are unpatentable under 35 U.S.C. §103(a) over Gibson (WO 96/07901) in view of Barisci (Trends in Polymer Science, 1996) and Casella (Analytica Chimica Acta, 335:217-225, 1996), Thackeray *et al.* (J. Phys. Chem., 90(25):6674-6679, 1995), Yamato *et al.* (Synth. Met. 87:231-236, 1997), Naarmann (DE 3,728,452), Li (Materials Research Society Symposium Proceedings, 1995), Sakaguchi (JP 4-2958), Stetter (U.S. Patent 5,512,882) or Wampler (Chem. Mater. 7(3):585-592, 1995).

The Examiner has alleged that claims 114, 116, 136, 138 and 158 are unpatentable under 35 U.S.C. §103(a) over Gibson (WO 96/07901) in view of Barisci (Trends in Polymer Science, 1996) and Casella (Analytica Chimica Acta, 335:217-225, 1996), Thackeray *et al.* (J. Phys. Chem., 90(25):6674-6679, 1995), Yamato *et al.* (Synth. Met. 87:231-236, 1997), Naarmann (DE 3,728,452), Li (Materials Research Society Symposium Proceedings, 1995), Sakaguchi (JP 4-2958), Stetter (U.S. Patent 5,512,882) or Wampler (Chem. Mater. 7(3):585-592, 1995) as applied to claims 108, 113, 115, 128, 135, 137 or 152 above, and further in view of Breheret (Colloq. Inst. Natl. Rech. Agron. 75:103-107, 1995), Mifsud (U.S. Patent No. 5,801,297; Mifsud I) and Mifsud (WO 95/08113; Mifsud II), Moy (Bioflavour 95(75):55-58, 1995) or Persaud (WO 86/01599).

(b) 35 U.S.C. §112, Second Paragraph Rejection

Appellants note that the 35 U.S.C. §112, Second Paragraph rejection raised in the non-final Office Action mailed January 25, 2005 has been withdrawn.

(c) New Grounds of Rejection

The Examiner has alleged that claims 98-110, 112-123 and 126-159 are newly rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-31 of U.S. Patent No. 6,631,333. Appellants submit that this is, in fact, not a new ground of rejection as it was presented in the Examiner's Answer mailed July 22, 2005; however, to be fully compliant Appellants address these new grounds of rejection below.

(7) Arguments

I. REJECTION UNDER OBVIOUSNESS-TYPE (NON-STATUTORY) DOUBLE PATENTING

Claims 98-110, 112-123 and 126-159 are allegedly newly rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 1-31 of U.S. Patent No. 6,631,333. Appellant submit that this rejection is improper.

U.S. Patent No. 6,631,333 ('333 Patent) is not prior art to the present application. The '333 Patent's earliest priority date is June 19, 1999, and is directed to methods and systems of remote characterization of an odor. The present application claims priority to a provisional application filed October 2, 1998 (eight months prior to the '333 patent priority date), wherein the provisional discloses (as one embodiment) a PANI-Polymer film comprising carbon-black (*i.e.*, a conductor and materially different conductor).

Accordingly, the Non-statutory Obviousness-type Double Patenting rejection is citing a patent (the '333 patent) based upon a later filed application. Under such circumstances the question is whether the time-wise extension alleged is justified or unjustified (MPEP 804). As the Board will note there can be no time-wise extension of the present application beyond that of the '333 Patent. The present application, by statute, will expire prior to the cited '333 Patent.

Furthermore, MPEP 804 indicates there are two tests applicable under Non-statutory Obviousness-type Double Patenting. First, there is the "one-way obviousness" test - this test is applicable when the *application being rejected is the later filed application* or both are filed on the same day. The test applied is based upon whether a claim pending in the "application at issue" would be anticipated by, or obvious in view of, an earlier filed application. This is the test that is being applied by the Examiner. The use of this test is in error in the present case. As noted above, the present application (*i.e.*, the application at issue) is the earlier filed application and thus this test does not apply. Appellants indicated this error in the Appellants' Reply Brief filed September 22, 2005.

The second test or the "two-way obviousness" test is applicable where the patent being cited (*i.e.*, the '333 patent) is the later filed application. A two-way test is applicable where (1) the applicant could not have filed the claims in a single

application *and* (2) there is administrative delay. (MPEP 804, citing to *In re Berg*, 46 USPQ2d 1226 (Fed. Cir. 1998)). The prosecution history of the present application demonstrates the on-going delay during the Examination process satisfying prong two. Furthermore, Appellants submit that the two applications could not be filed as a single application without changing inventorship, ownership, priority, etc.

For the foregoing reasons, Appellants submit that the Non-statutory Obviousness-Type Double Patenting rejection should be withdrawn because (1) the standard applied in the present rejection is improper based upon recognized case law, (2) even if the correct standard was applied the test would demonstrate that the inventions could not have been filed in the same application and that there was administrative delay within the Patent Office, and (3) there would be no time-wise extension since the application at issue is the earliest filed application.

II. REJECTION UNDER 35 U.S.C. §103

The Arguments provided in the Appeal Brief filed November 5, 2004, are incorporated herein by reference.

A. REJECTION OF CLAIMS 98-110, 112-113, 115, 117-123, 126-135, 137, 139-157 AND 159 OVER GIBSON IN VIEW OF BARISCI AND FURTHER IN VIEW OF CASELLA, THACKERAY *ET AL.*, YAMATO, NAARMANN, LI, SAKAGUCHI, STETTER OR WAMPLER

1. The Technology

The sensor systems for the purpose of this appeal can be divided into two general categories: (i) conductimetric sensors and (ii) amperometric sensors (sometimes referred to as electrochemical sensors).

Conductimetric sensors are taught in Gibson *et al.* and electrochemical sensors are taught in Casella, Thackeray, Yamato, Naarman, Li, Sakaguchi, Stetter or Wampler, as previously described (see, *e.g.*, Appellants Brief, April 25, 2005). Barisci describes both systems having independent properties, measurement capabilities and processes.

a. Conductimetric Sensors

An embodiment of a structural schematic and system of a conductimeteric sensor and system of the invention is provided in Figure 1 of Appellants' Appeal Brief, filed November 5, 2004. As described in Appellants' Brief, Figure 1 shows two conductive leads (**10**) on opposite ends and separated by a sensing area (**20**). A sensing area can be disposed upon a non-conductive substrate, backing, or other material (**30**). The sensing area comprises a conductive organic material (**40**) and a conductive material compositionally different than the conductive organic material (**50**). An electrical measuring device (**60**) is coupled to the conductive leads (**10**) and measures, for example, the resistance change between the leads (*e.g.*, the resistance change of the sensing area).

During operation the sensing area (**20**) directly absorbs, adsorbs or imbibes an analyte (**70**). The analyte causes the conductive materials to change (*e.g.*, by polymer swelling) thereby inducing a measurable change in resistance as measured by an electrical measuring device (**60**). This change in resistance is used to determine if a particular analyte or class of analytes is present in a sample.

In the Examiner's Answer mailed January 25, 2005, and in the Substitute Examiner's Answer mailed March 19, 2007, the Examiner alleges that the representation in Figure 1, provided in the Appeal Brief is not an accurate representation of the different sensor types because Figure 1 appears to show the regions as regular stacked, separate, alternating regions rather than the random regions that exist. Appellants respectfully submit that Figure 1 provides a "general" representational and "an embodiment" schematic of the invention. The materials can be random or stacked, as depicted.. For example, the specification teaches that ink-jet printing techniques can be used wherein the different materials can be selectively deposited in an ordered manner (see, *e.g.*, page 44, lines 1-13); this is the embodiment that is depicted in the Figure provided in Appellants' Brief.

b. Amperometric-Electrochemical Sensors

A general structural schematic and system of an amperometric-electrochemical sensor was provided in Figure 2 in the November 5, 2004, Appeal Brief. With reference to Figure 2 there is shown three electrodes (**10A-C**) each connected to an electrical measuring device (**20**) by a single conductive lead (**30**).

An amperometric-electrochemical sensor system requires additional

electrodes immersed in a liquid electrolyte. Each electrode (**10**) is attached to a circuit using a single conductive lead (**30**). The electrons (**40**) involved in the electrochemical reaction flow from the working electrode (**10a**) through the external circuit (**50**), producing the output signal of the sensor. During operation the materials of the electrodes are selected such that they do not change in resistance as that would defeat the function of the amperometric-electrochemical sensor system. An analyte is contacted with, for example, an aqueous buffer (**60**) that is in contact with a sensor. The analyte causes a change in the ionic species present in the electrolyte liquid.

In electrochemical sensor systems (including potentiometric and amperometric), the sensor signal or current, "I", deriving from the electrooxidation at an electrode in an electrochemical sensor is proportional to, for example, the partial pressure of the analyte to be measured at constant potential "U". For two electrode sensors (as depicted in Barisci at Figure 2(a) and in the Examiner's Answer at page 8, Substitute Examiner's Answer at page 9), there is a constant potential between the sensing and auxiliary electrode. In a three electrode system a potentiostat keeps the potential constant between working and counter electrode. The three electrode configuration (shown in Barisci at Figure 2(b) and in the Examiner's Answer at page 8, Substitute Examiner's Answer page 9) allows for precise operation and measurement of "ion-electron flow".

A three electrode electrochemical (*e.g.*, amperometric) sensor system consists of five major parts: an electrolyte, a working electrode (W), a counter or reference electrode (R), an auxiliary electrode (A) and a potentiostat (see, *e.g.*, Figure 2(b) of Barisci and the Figure 2(b) at page 8 of the Examiner's Answer, Substitute Examiner's Answer page 9). Each part of the sensor influences the overall performance and analytical characteristic of the sensor. The analyte gas may pass through a filter prior to entering the system which removes unwanted substances or alters the analyte ionic species. The electrolyte is often a concentrated aqueous solution sufficient for maintaining ionic species. The working electrode is typically a noble metal with a layer of conductive polymer (with or without a catalyst). The two remaining electrodes, the auxiliary and reference electrodes are located within the body of the system in the bulk of the electrolyte solution. The reference electrode is used to maintain the working electrode at a known electrochemical potential, is preferably not exposed to the analyte ionic species and

must be stable in the electrolyte. The auxiliary electrode completes the electrochemical cell by performing the half-cell reaction, the nature of which is in opposition to the sensing electrode reaction. The measured current arises from the electrochemical oxidation or reduction of the electrode surface. The type of reaction, oxidation or reduction, determines the sign of the sensor signal. A potentiostat and associated electronics are part of the sensor operation. A potentiostat is used with the three electrode sensor to provide a fixed potential for the working electrode relative to the reference electrode in the electrolyte. Apart from applying a voltage bias to the working electrode the potentiostat is used to convert the sensor's current signal to a voltage for measurement.

In amperometric-electrochemical sensors, the resistance of the electrode body is not sensed at all to produce a registered signal. Rather, charge flow *across* the electrode/solution interface is sensed. The material of an amperometric-electrochemical sensor experiences both (i) a flow of electrons and (ii) a flow of ions into, onto or out of the material. In this manner the sensor of the electrochemical system undergoes an oxidation or reduction thereby changing electron flow through the system between a cathode electrode and an anode electrode. While the resistance of the electrode body is determined by the composition and arrangement of the electrode body the electrode preferably does not change resistance. Charge flow across the electrode/solution interface is determined by a variety of other factors, including the capacitance between the electrode and the solution and the availability of electronic states at the electrode surface that can participate in charge transfer with species in the solution. Accordingly, the *analyte does not come into direct contact with the sensor otherwise charge cannot flow through the circuit*.

Amperometric-electrochemical sensors serve certain uses in particular areas of sensing oxidation-reduction (*e.g.*, pH sensing), but have limited utility in the areas of identifying analytes. In particular, electrodes in electrochemical systems can undergo degradation, usually caused by over-oxidation occurring during electrochemical cycling (see, *e.g.*, Sestak at page 118, second full paragraph under "Introduction"; Sestak is of record in the present case).

Furthermore, the materials chosen to act as electrodes in amperometric-electrochemical sensors are selected based, at least in part, on the fact that their conductivity is not "sensed" in the amperometric-electrochemical sensor and preferably does not change during operation. Accordingly, one of skill in the art

would not look to or expect that materials present in amperometric-electrochemical electrodes would be useful in a conductimetric sensor for the simple fact that they are not intended and would not function properly if they were to change conductivity. This "invisibility" is inapposite to the role of sensing materials in conductimetric sensors. Indeed, "sensing" the conductive properties of amperometric-electrochemical sensor electrodes will render the electrodes unfit for their intended use as sensors in amperometric-electrochemical systems. In fact, it is not the case at all that materials that are good electrochemical detectors will make good chemiresistors. Thus, obviousness does not flow from one to the other. An example of this is the use of ferrosine-modified enzymatic sensors to detect glucose. These are good electrochemical sensors but are completely ineffective as chemiresistors because in fact they are electronically resistive to DC current in both the oxidized and reduced states. This property is what makes such ferrosine modified enzymatic sensors useful as an amperometric sensor to detect a glucose analyte by way of a change in an ion flow and charge flow into the film.

<u>2. The Cited References</u>

The references can be divided into two general categories similar to the categories of "Technology" discussed above (*i.e.*, conductimetric and amperometric-electrochemical sensors).

The Examiner has kindly provided translations of the Naarmann and Sakaguchi references. The translations are cumulative to the references of record. For example, Naarmann generally describes the making of polymers and in general that the polymers can be used in electrical storage device and as electrodes and sensors. Naarmann fails to describe any sensors. Sakaguchi identifies the problem to be solved as "the electrodes become used up after several months" in galvanic-cell gas sensors (see, Sakaguchi translation at page 3, bottom of page to page 4). Such galvanic-cell systems are described whereby the "electrode reactions oxidizes or reduces electrochemically the gas being detected and extracts the electricity flowing in an external circuit at the time as sensor output." (See, Sakaguchi translation at page 3, lines 13-15). As described above, the sensors described in Sakaguchi are REDOX-based sensors. For example, Sakaguchi describes at page 7 of the translation, "Examples of gases to be detected are....any gas which causes redox reactions..." (see, Sakaguchi at page 7, lines 1-5). Furthermore, as described

herein, the use of an electrolyte to "bathe" the electrode is required in electrochemical sensing systems. Appellants direct the Examiner and the Board to page 12, lines 7-13, which describes the use and proper selection of electrolyte solutions to use the electrochemical sensors described in Sakaguchi (see, also, page 13-14, "Embodiment 1"). Sakaguchi describes the operating principals of electrochemical sensor systems and demonstrates that the operating conditions and functions are not interchangeable.

The Examiner alleges at page 15, lines 1-11, of the Office Action mailed January 25, 2005, and page 17, lines 10-19 of the Substitute Examiner's Answer mailed March 19, 2007, that it would be obvious to one of ordinary skill in the art at the time the invention was made to:

> ...incorporate the teachings of Casella[, de Lacy Costello], Thackeray [*et al.*], Yamato, Naarmann, Li, Sakaguchi, Stetter or Wampler relative to the incorporation of conductors such as carbon black, anions of tetrathiafulvalene derivatives, metal particles or metal oxide into the conductive organic polymers used in the sensing arrays of Gibson because of their sensitivity to known analyte gases or enhanced sensing and/or stability properties as taught by each of Casella, Thackeray [*et al.*], Yamato, Naarmann, Li, Sakaguchi or Wampler compared to sensors made with only the conductive polymers taught by Gibson and the recognized ability and expectation of the Gibson conductive polymers to be affected by interactions in a number of sensing formats in a manner that change the electronic structure and as a result the resistivity of the polymer as shown by Barisci.

Appellants submit that Casella, Thackeray *et al.*, Yamato *et al.*, Naarmann, Li, Sakaguchi and Wampler do not teach materials useful to serve as analyte gases, but rather teach materials that promote catalysis in REDOX reactions and thus serve as amperometric-electrochemical sensors. Furthermore, Barisci teaches different sensor systems including the importance that in amperometric-electrochemical sensors that the electrode materials remain capable of conducting ions and electrons, which is contrary to the function of Appellants' claimed invention.

Appellants respectfully submit that the Examiner has not set forth a *prima facie* case of obviousness. A *prima facie* case of obviousness requires that three criteria be met. MPEP §2143. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Even in the absence of a suggestion or motivation, the unexpected properties and function demonstrate the non-obviousness of the present invention. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or

references when combined) must teach or suggest all the claim limitations. Any teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP §2143.

Even absent the requirement of "teaching, suggestion, or motivation" (TSM) test, Appellants submit the claims are non-obvious. Appellants submit that the purpose of the Patent System is to reward inventors for advancing technology. As described more fully below, the invention provides sensor and sensor systems that advance technology by increasing the sensitivity to particular analytes. In addition, the combination of the elements of the invention result in a sensor material and sensor system that functions differently than what was known in the art at the time of filing. As the U.S. Supreme Court stated in *KSR International Co. v. Teleflex Inc. et al.*:

> For over a half century, the Court has held that a "***patent for a combination which only unites old elements with no change in their respective functions***...obviously withdraws what is already known into the filed of its monopoly and diminishes the resources available to skillful men."

U.S. Supreme Court No. 04-1350, Slip Op. at 11-12 (April 30, 2007) (emphasis added). As demonstrated below, the invention is not a mere combination of old elements but a combination that results in a system that functions in a different manner resulting in unexpected sensitivity to certain analytes compared to amperometric sensors and resistometric sensor composites. This type of advancement in the technology should be rewarded based upon the public policies of the Patent System.

Determining obviousness under 35 U.S.C. §103 requires an analysis of the claimed invention as a whole, and focusing on the obviousness of substitutions and differences, instead of on the invention as a whole, is a legally improper way to simplify that determination. *Gillette Co. v. S.C. Johnson & Son Inc.*, 16 USPQ2nd 1923, 1927 (Fed. Cir. 1990). Thus, changes from the prior art, whether or not "minor", must be evaluated in terms of the whole invention, including whether the prior art provides any teaching or suggestion to one of ordinary skill in the art to make such changes to produce the claimed invention. *Northern Telecom Inc. v. Datapoint Corp.,* 15 USPQ 2nd 1321, 1324 (Fed. Cir. 1990). Here, the Examiner is

substituting materials that serve different purposes. In addition the materials are selected based upon different properties (*i.e.*, the materials of amperometric sensors are selected, in part, because they do not change conductivity).

The Examiner alleges a combination of no less than three references would result in the claimed invention. However, there is no suggestion in any of the references for the proposed combination. As the CAFC stated in *ACS Hospital Systems Inc. v. Montefiore Hospital*, 221 USPQ 929, 933 (1984):

> Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so.

In order to justify the combination of references proposed by the Examiner one of skill in the art would be required to discard teachings in the art indicating that (1) polymer sensors are not sensitive to analytes (see, *e.g.*, Breheret and Mifsud I and II), (2) that polymer materials in amperometric-electrochemical sensors undergo degradation (see, *e.g.*, Sestak), and (3) that materials that are selected in amperometric sensors are useful because they don't change conductivity. One of skill in the art would be required to discard the fundamental different operating conditions and principles of materials used in amperometric-electrochemical systems, namely that the materials be invisible to the system (*i.e.*, they do not change their ability to conduct ions or electrons), to arrive at Applicants' invention which necessitates that the materials undergo a change in conductivity when contacted with an analyte.

The prior art must suggest the desirability of the claimed invention. MPEP §2143.01. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine,* 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones,* 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992); MPEP §2143.01. As will become readily apparent from a review of the references cited in the pending rejection, the proposed combination would require that one of skill in the art discard the fundamental principles and necessity of selecting materials for amperometric-electrochemical

sensors based upon their ability to conduct ions and electrons and believe, without any suggestion in the art, that these materials would be useful as materials that change conductivity in conductimetric sensors and systems. The combination would require that one of skill in the art discard the requirement of electron and ion flow in amperometric-electrochemical systems and leap to a conclusion that amperometric-electrochemical materials are useful in systems, such as Appellants'. Furthermore, one of skill in the art would be required to discard teachings that polymer materials, although lacking sensitivity and usefulness, would be useful in composite materials in conductimetric sensors.

In the references presented in the pending rejection numerous references actually teach away from the combination. For example, Breheret and Mifsud I and II actually teach away from the use of the polymer materials found in Gibson. Furthermore, Sestak teaches away from amperometric-electrochemical materials as they degrade due to oxidation. Accordingly, one of skill in the art would not be motivated to combine polymer sensors or amperometric-electrochemical sensors to arrive at Appellants' invention. As indicated in *In re Ratti*, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti,* 270 F.2d 810, 123 USPQ 349 (CCPA 1959); MPEP §2143.01.

Appellants' respectfully submit that when viewed as a whole, the combination of references proposed by the Examiner is based upon hindsight. In particular, the Examiner has combined certain references that have nothing to do with the invention as a whole, but are combined merely because they might possibly teach an element of Appellants' claims, even when such references are from non-analogous art (*e.g.*, the Wampler reference). It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. *In re Gorman*, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). *See also Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985)). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988); *In re Fritch*, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992).

Accordingly, Appellants respectfully submit that a *prima facie* case of obviousness has not been provided because (1) there is no motivation to combine or modify the references as suggested by the Examiner, (2) the combination is based upon hindsight reconstruction, (3) that the combination would require that one of skill in the art discard fundamental principles of sensor operation, and (4) that when combined the references fail to teach or suggest each and every element of Appellants' claimed invention.

a. Differences in Electrochemical Material Selection vs. Conductimetric Material Selection

Referring now to the Figure depicted at Page 8 of the Examiner's Answer and page 9 of the Substitute Examiner's Answer (*i.e.*, Barisci, Figure 1 and 2), there is shown in Figure 1 electroactive polymers with a couterion ("A^-"). Figure 1 demonstrates the applicability of the REDOX changes to conductive polymers. For example, Figure 3 of Barisci shows an equation depicting oxidation and reduction of polypyrrole (*i.e.*, Figure 1(i)). The analyte interacts with the electrolyte solution bathing the electrode to modify the counterion in solution to influence current movement through the system. The analyte does not interact with the sensing area directly as recited in, for example, claim 98, 104, 105, 108, 126, and 128 ("...wherein the sensing area is in direct contact with a vapor...").

Figure 2 shows a potentiometric measuring technique. In potentiometric measurements performed on systems such as that depicted in Figure 2(a), there is no current through the system. Thus, there can be no change in resistance. In potentiometric sensors, the analytical information is obtained by converting the recognition process into a potential signal, which is proportional (in a logarithmic fashion) to the concentration of ionic species generated or consumed. Such devices rely on the use of ion selective electrodes for obtaining the potential signal.

Figure 2(b) depicts a 3 electrode system. In a 3 electrode system an externally applied potential is required due to the potential drop across the cell due to ***the solution resistance*** (*i.e.*, potential drop (E) – current (i) x solution resistance (R)) and the polarization of the counter electrode that is required to complete the current measuring circuit. In a three electrode system the potential of the working electrode is controlled relative to the reference electrode, and a current passes

between the working electrode and the auxiliary/counter electrode (depicted as "i" in Figure 2(b) at page 8). Accordingly, there is no resistance measurement with respect to an analyte adsorbing to a polymer, rather the measurement is a current measurement (converted to voltage) produced by the ion changes in the electrolyte solution.

According to the Examiner, one would allegedly arrive at Appellants' claimed invention by taking the primary reference (Gibson), combining it with the secondary references based upon motivation provided by a third reference, Barisci. Following the Examiner's reasoning, one of skill in the art would be taught, by Gibson, that polymer and polymer layers serve as sensing materials in conductimetric sensors. Turning then to the secondary references, one of skill in the art upon reading Casella, Thackeray, Yamato, Naarman, Li, Sakaguchi, Stetter or Wampler would conclude that the materials used in amperometric sensors of the cited references (*e.g.*, PANI-Pt materials) are (1) inert, (2) stable, (3) conduct electrons and (4) do not change resistance upon contact with an analyte, which is supported by the data collected and presented in those sensor systems. For example, at page 224, "Conclusions," Casella states, "The novelty of this study lies in the use of PANI films in alkaline media as an ***inert*** and stable organic matrix of copper-catalytic species." (Emphasis added). Turning finally to the reference that allegedly provides motivation, Barisci, one of skill in the art would conclude that polymer materials (*i.e.*, non-composite materials), serve as materials useful in conductimetric systems (cumulative to Gibson) and that such polymers have properties useful in redox reactions in electrochemical systems. A lack of motivation can be found when the alleged motivation to combine references requires that the teachings of the prior art references be modified such that the prior art technology does not function for its intended purpose. Such is the case in the obviousness rejection of record.

The translations of Naarmann and Sakaguchi do not change this interpretation and are cumulative to the other secondary references.

Appellants submit that in order to arrive at the Examiner's position with respect to the claims, one of skill in the art would have to disregard what is taught by the references being relied upon by the Examiner and to imply a function in electrochemical (*e.g.*, amperometric) systems that, in fact, would render the systems non-functional (*i.e.*, that the sensor materials of the secondary references "change

electronic structure", see Examiner's Answer at page 16; Substitute Examiner's Answer at page 17).

The Examiner alleges that it would be obvious to substitute materials in electrochemical sensor systems into a system that functions in a different manner. In performing this "substitution" the Examiner indicates that electrochemical sensors, and the material used therein, measure resistance (see, *e.g.*, page 7, lines 23-26 of the Examiner's Answer). However, by stating that electrochemical systems measure resistance, the Examiner has modified and changed the way electrochemical sensors operate (*i.e.*, rendering the materials used in the electrochemical sensor useless for their intended purpose). In other words, if the electrode materials in electrochemical systems increased in resistance, as alleged by the Examiner, the materials used in the electrodes would not be useful for their intended purpose. For example, if the polymer materials on an electrode in an electrochemical system increased in resistance due to imbibing, adsorbing, or absorbing an analyte or other contaminant, all current flow would cease in the system and the system would no longer function to measure the presence of an analyte (*i.e.*, the system would cease to function in the manner in which it was designed).

The Examiner is substituting materials that serve different purposes and are selected for use in the particular systems based upon different properties, *i.e.*, the materials of amperometric sensors are selected, in part, because they do not change conductivity upon contact with an analyte, whereas the materials in conductimetric sensors are selected because they do change conductivity when contacted with an analyte. In other words, one of skill in the art would NOT want to use materials that increase in resistance in electrochemical systems because it would render the systems unfit for their intended purpose. Thus, if one of skill in the art were to develop sensors of the present invention (*i.e.*, sensors that change resistance when contacted with an analyte), the person of skill in the art would NOT look to electrochemical systems because the materials in electrochemical systems are specifically selected on the basis that they do NOT change resistance upon contact with an analyte. To modify the teachings of the secondary references to ignore this fundamental difference, as suggested by the Examiner, is to modify the art in such a manner that renders electrochemical sensors inoperable.

Appellants submit that the Examiner has focused substituting one material for another without examination of the differences in the art with respect to the use of

the material and the properties necessary for such use in electrochemical sensor systems. Such modifications and combination render the prior art references being relied upon unfit for their intended purpose thus demonstrating the lack of motivation relied upon by the Examiner.

A basis for the Examiner's motivation to combine the references can be found in the apparent misunderstanding in the operation of electrochemical sensors as set forth in the Examiner's Answer at page 7, lines 23-26, Substitute Examiner Answer at page 7,bottom, to page 8),

> In 2(b) [of Barisci] the working electrode is separated from the other two electrodes by the polymer layer so that in all instances the potential, current or *resistance being measured is measured through the conducting polymer layer.*

(Emphasis added). Appellants respectfully submit that one of skill in the art will recognize that the working electrode is in direct electrical communication with the reference and counter electrode and are not "separated from the other two electrodes by the polymer layer". Furthermore, the polymer layer does not serve as a barrier such that "potential, current or resistance [is] measured through the conducting polymer." Rather the conducting polymer serves to facilitate electron transfer from an ionic species in the electrolyte solution to the electrode. Because of the polymer layer's role in electrochemical systems, it is important that the polymer layer not change its ability to conduct electrons (*i.e.*, does not change its ability to facilitate electron transport). Appellants submit that the working electrode should be electrochemically inert (*i.e.*, that ideally the electrochemical sensor does not imbibe the analyte to be measured thus becoming "poisoned"). Appellants have not provided such basic references as the knowledge is common in the art. The fact that a working electrode should preferably be "invisible" or inert is common knowledge in the art. It is also common knowledge that if a material adsorbs to the surface of a working electrode (*e.g.*, a polymer layer), that the electron transfer process will degrade and the amperometric system will cease to function, thus defeating its use as a sensor in electrochemical systems. Where an electrode in such systems becomes "poisoned" by the analyte, the electrode (*e.g.*, polymer layer) must be cleaned in order to maintain the sensor's functionality. Sensor materials that are easily poisoned are not suitable for use in electrochemical sensors.

The Examiner alleges that Appellants do not cite any support for the position that the materials used in electrochemical systems should be "invisible". Appellants respectfully direct the Examiner and the Board to, for example, Casella at page 224, "Conclusions," wherein Casella states,

> The novelty of this study lies in the use of PANI films in alkaline media as an ***inert*** and stable organic matrix of copper-catalytic species.

(Emphasis added). Appellants previously used the term "invisible" to refer to the inert nature of the material (*i.e.*, that it does not change in a manner that is sensed by the system). If an electrode is not inert it becomes "poisoned". Poisoning is the process which takes place when interference gases or analytes bind to the active material in the sensors' electrodes, thus reducing their efficiency.

Appellants respectfully submit that in electrochemical (*e.g.*, amperometric) systems, "resistance" is not measured; an increase in the resistance of a polymer is detrimental to the system's function and a change in the polymer layer due to absorbing an analyte is very undesirable. In fact, if the electrode materials of amperometric and potentiometric systems increased in resistance, the sensing system would fail to function. What is measured in amperometric systems is the flow of electrons, measured as voltage.

Electrochemical (*e.g.*, amperometric/potentiometric) sensors are based on the detection of electroactive species involved in the chemical or biological recognition process through electron transfer (*i.e.*, conversion of a chemical ionic charge to an electric charge). The signal transduction process is accomplished by controlling the potential of the working electrode at a fixed value (relative to a reference electrode) and monitoring the current as a function of time. The applied potential serves as the driving force for the electron transfer reaction of the electroactive species. The resulting current is a direct measure of the rate of the electron transfer reaction. Barisci describes this well at page 308, second column, lines 29-31,

> Amperometric detection is based on the fact that the analyte will modify the ***current produced*** by the oxidation/reduction of the polymer (Fig. 3).

(Emphasis added). Accordingly, a change in resistance of the working electrode in an electrochemical system (*i.e.*, an increase in resistance) would result in an amperometric system that would cease to function properly as there could be no

conversion of ion species to electron species (*i.e.*, no redox reactions would occur and no current would be produced). Thus, in electrochemical systems the movement of electrons is critical to the system's function, a change in electron movement in the polymer due to, for example, poisoning by an analyte thereby increasing the resistance in the polymer would cause the amperometric system to not function for its intended purpose.

The use of amperometric sensors to detect analytes by measuring resistance would be to use the amperometric system in a way that defeats its function/purpose. Thus, the alleged teaching relied upon by the Examiner (*i.e.*, that amperometric systems measure resistance) defeats the fundamental principle of operation of an amperometric system. The systems depicted in Figure 2 of Barisci (and at page 8 of the Examiner's Answer, page 9 of the Substitute Examiner's Answer) would not function properly if the polymer present on those electrodes changed resistance by absorbing an analyte. As the courts have indicated, the proposed modification of a reference to provide a case of obviousness cannot render the prior art unsatisfactory for its intended purpose. <u>If the proposed modification would render the prior art unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification</u>. *In re Gordon,* 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); MPEP §2143.01 (Emphasis ours; *see, also*, *In re Ratti,* 270 F.2d 810, 123 USPQ 349 (CCPA 1959)).

In contrast to the potentiometric and amperometric systems, conductimetric sensors are designed to adsorb, absorb, and imbibe analytes. In other words in conductimetric sensors it is desirable to have a sensing material (*e.g.*, a polymer material) that reacts with the analyte by adsorbing the analyte on to the sensor material resulting in a change in resistance. This is in direct opposite to the types of materials that are selected to serve in potentiometric and amperometric sensor systems.

<u>b. Sensitivity to Analytes</u>

Contrary to the Examiner's statements in the Examiner's Answer, Appellants submit that Casella, Thackeray *et al.*, Yamato *et al.*, Naarmann, Li, Sakaguchi and Wampler do not teach materials that are sensitive to known analyte gases, but rather teach materials that promote catalysis in REDOX reactions and thus serve as amperometric-electrochemical sensors. In amperometric-electrochemical sensors

an electrochemical conversion occurs at the polymer interface. In electrochemical sensors ionic species transfer their electrons to or from the polymer material to cause electron flow and that the "gas analyte" is not required to come into direct contact with the sensing material.

The Examiner's alleges Appellants' argument regarding the secondary references not teaching materials that are sensitive to known analyte gases are irrelevant to the pending claims (see, *e.g.*, Examiner's Answer at page 20, bottom, to page 21, top; Substitute Examiner's Answer at page 22). However, Appellants did not provide the argument to address the claims, but to address the alleged motivation set forth by the Examiner as stated at page 15, bridging to page 16 of the Examiner's Answer(Substitute Examiner's Answer at page 17):

> ...incorporate the teachings of Casella, Thackeray, Yamato, Naarmann, Li, Sakaguchi, Stetter or Wampler relative to the incorporation of conductors such as carbon black, anions of tetrathiafulvalene derivatives, metal particles or metal oxide into the conductive organic polymers used in the sensing array of Gibson ***because of their sensitivity to known analytes gases or enhanced sensing and/or stability properties as taught by each of Casella, Thackeray, Yamato, Naarmann, Li, Sakaguchi or Wampler*** compared to sensors made with only the conductive polymers taught by Gibson and the recognized ability and expectation of the Gibson conductive polymers to be affected by interactions in a number of sensing formats in a manner that change the electronic structure and as a result the resistivity of the polymer as shown by Barisci.

(Emphasis added). Appellants submit that none of the cited references teach a polymer that is sensitive to known analytes but rather that the polymers are useful in detecting an analyte through redox reactions. In other words, the polymer is not sensitive to the analyte, rather the polymer is sensitive to ions produced in the amperometric system of the references. Such ions can be from any number of ionic species and thus the sensors are non-specific. Thus, one of skill in the art would not be motivated to utilize the polymers of Casella, Thackeray, Yamato, Naarmann, Li, Sakaguchi or Wampler because they are ***not*** sensitive to known analytes as alleged by the Examiner, but are rather sensitive to ions (*i.e.*, any charged atom).

c. Composite Materials

At page 11, lines 6-9 of the Examiner's Answer (Substitute Examiner's Answer at page 12, lines 6-9), the Examiner states,

> In the first paragraph of page 311 [of Barisci], a discussion of composite materials in which the conducting polymer is combined with another material. These composite materials showed improved reproducibility when used as

> sensors, adequately compensating for any problems due to an expected lower sensitivity.

Appellants submit that the paragraph referred to at page 311 of Barisci does not describe inorganic materials (as recited in Appellants' claims) and furthermore teaches that the composite "is not a true composite, but a graft copolymer." (See, *e.g.*, Barisci at page 311, lines 8-12).

The Examiner's Answer further misconstrues Stetter. At page 16, beginning at line 7-8 of the Examiner's Answer ((Substitute Examiner's Answer at page 16, lines 7-8), the Examiner indicates, "The sensor comprises a polymer whose physical structure is altered by the vapor. . ." The Examiner goes on to allege that the sensor comprises conductive particles such as copper, silver gold, platinum and the like (see, *e.g.*, the Substitute Examiner's Answer page 16, lines 16 through 18). Appellants respectfully submit that Stetter teaches the use of a chemiresistive layer comprising a mixture of conductive particles and an ***insulator*** (*e.g.*, an elastomer/polymer, see, column 3, and lines 5-9 of Stetter). Various polymers are identified at column 4, lines 49-55, and consist of ethylene propylene, styrene butadiene, silicone, fluorsilicone, butyl rubber, isobutylene isoprene, chloroprene, fluorocarbon and polyacrulate, all commonly used insulating polymers. Thus, Stetter does not teach a mixture of two compositionally different ***conductive*** materials, but to the contrary teaches and suggests only mixtures of conductive material and non-conductive material. Appellants further show in the specification that the composite sensors of Appellants' invention have improved and unexpected sensitivity compared to composites of insulating polymer composites such as those in Stetter, thus demonstrating unexpected results (see, *e.g.*, the Appellants' specification at Figure 4 and page 15, lines 12-18).

d. Analyte Contact with Sensor Material

At page 20, lines 14-17, of the Examiner's Answer (page 21-22), the Examiner states,

> Thus Appellant's statement in the second full paragraph of page 5 of the Brief that the analyte does not come into direct contact with the sensor, is not consistent with the structure or description of these references.

Appellants respectfully submit that the molecular entity that comes in contact with the sensor material in the cited references (*i.e.*, Casella, Thackeray, Yamato, Naarman, Li, Sakaguchi, Stetter or Wampler) is an ion (*i.e.*, an electrically charged

atom) and can in fact be any charged ion. For example, Yamato *et al.* teach an electrode for electrochemical measurements. Yamato *et al.* teach sensors having on their surface glucose oxidase (GOD) (see, Yamato *et al.* at page 235, first column, section 3.2). The purpose of the enzyme linked to the surface of the sensor is to oxidize glucose (see also, Barisci at page 309, 5th full paragraph).

The glucose oxidase catalyzes the conversion of glucose to gluconolactone (2*e* oxidation). The electrons are then shuttled to the polymer material on the electrode where the ion undergoes electron-transfer (*i.e.*, reduction) with the polymer to produce the amperometric current. As will be noticed, the analyte, glucose, does not cause a change in the polymer film in this electrochemical system. In other words, the oxidized ion is then used to cause a change in the potential across the system resulting in the production of current and thus an indirect detection of glucose. Glucose does not come into contact (*i.e.*, imbibe, adsorb, absorb) to the sensor material, rather the ion generated by the oxidation of glucose causes a measurable change in the production of current in the system.

e. Teaching Away

Furthermore, the Examiner is picking and choosing references in the art to satisfy the motivation to combine. For example, the Examiner states,

> Relative to the alleged teaching away by the Breheret and Mifsud references, examiner responds that Appellant has not limited the type of gases being sensed...It is also noted that these references are only applied relative to the claims that require additional structure....

(see Examiner's Answer at page 21, lines 20-26, Substitute Examiner's Answer page 23, 6-12). Appellants submit that the teaching away in Breheret and Mifsud is also not specific to any particular gases or polymer sensors and are directed to the sensor class as a whole. The Examiner wishes to disregard this teaching and apply the references only to the dependent claims teaching additional structures. Although the references are applied to the claims with respect to additional structure, the teachings of the references encompass the state of the art as a whole. Thus, as a reference generally available to one of skill in the art, the teachings of Brehert and Mifsud are available to Appellants to demonstrate a lack of motivation to utilize polymer sensors and the Examiner cannot simply ignore the teachings as being irrelevant unless addressed to the specific claims. Furthermore, Sestak (of record)

teaches away from amperometric-electrochemical materials as they degrade due to oxidation.

Appellants are not attacking the references individually as alleged in the last paragraph at page 22 of the Examiner's Answer (1st full paragraph of Examiner's Answer page 23, lines 6-12. The Appellants are merely describing the teachings of each reference individually in order to present the lack of motivation and missing elements when the references are combined. In addition, Appellants address specific references because they teach the "inert" characteristic of amperometric sensors and furthermore teach away from the use of polymer sensors. By addressing the list of references "generally" or from a high level, as suggested by the Examiner, the teachings of the references are being overlooked or misconstrued. Appellants are demonstrating that the generalizations made in the obviousness rejection are not accurate and thus the references should not be construed as providing certain information when in fact they do not provide such information and/or teach away from such information.

In order to justify the combination of references proposed by the Examiner one of skill in the art would be required to discard teachings in the art indicating that (1) polymer sensors are not sensitive to analytes (see, *e.g.*, Breheret and Mifsud I and II), (2) that polymer materials in amperometric-electrochemical sensors undergo degradation (see, *e.g.*, Sestak), and (3) that materials that are selected in amperometric sensors are useful because they do not change conductivity. Furthermore, in order to arrive at the alleged motivation to combine the references one would have to modify the materials and systems in the secondary references such that they no longer function for their intended purpose (*i.e.*, that the material in the electrochemical sensors change in resistance). One of skill in the art would be required to discard the fundamental different operating conditions and principles of materials used in amperometric-electrochemical systems, namely that the materials be inert/invisible to the system (*i.e.*, they do not change their ability to conduct ions or electrons), to arrive at Appellants' invention which necessitates that the materials undergo a change in conductivity when contacted with an analyte.

For at least the foregoing reasons a prima facie case of obviousness has not been made.

Respectfully submitted,

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